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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/070,480      | 07/08/2002  | Takahisa Nakai       | 12178/2             | 4713             |

26646 7590 04/21/2005

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NEW YORK, NY 10004

EXAMINER

ODELL, LINDSAY T

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/070,480

Applicant(s)

NAKAI ET AL.

Examiner

Lindsay Odell

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Application Status*

1. Amendment of claims 5-7, 18-20, 22, 24, 26 and 31-32 by virtue of a preliminary amendment received February 28, 2002 is acknowledged. Claims 1-35, as amended, are pending.

### *Restriction*

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-3 and 5-7, drawn to a decarbamylase crystal having a space group  $P2_12_12$  and an amino acid sequence set forth in SEQ ID NO: 1.

Group II, claim(s) 1, 4-7, drawn to a decarbamylase crystal having space groups  $P2_12_12_1$  and an amino acid sequence set forth in SEQ ID NO: 2.

Group III, claims 8-13, drawn to methods for preparing a crystal of decarbamylase.

Group IV, claim(s) 14-21 and 31, drawn to decarbamylase having particular structural features.

Group V, claim(s) 22-30 and 32-33, drawn to methods or systems for designing decarbamylase mutants based on the stereostructure of decarbamylase.

Group VI, claim(s) 34-35, drawn to a recording medium describing a decarbamylase mutant involving inputting data of a crystal of an enzyme having decarbamylase activity.

Art Unit: 1652

3. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of Group I is a decarbamylase crystal having a space group  $P2_12_12$  and an amino acid sequence set forth in SEQ ID NO: 1. Group II is drawn to a decarbamylase crystal having space groups  $P2_12_12_1$  and an amino acid sequence set forth in SEQ ID NO: 2. The structure of the decarbamylase crystal of Group II, described by SEQ ID NO: 2 and space group  $P2_12_12_1$ , is different from the structure of Group I. Thus, the special technical feature of Group I is not shared by Group II.

The products of Groups IV and VI also do not share the special technical feature of Group I because they have different structural features from the decarbamylase crystal of Group I. While the products claims 17-20 of Group IV share particular active site residues of SEQ ID NO: 1, the structure of these products is different from the structure of SEQ ID NO: 1 in its entirety. In addition, the products of Group IV do not share the crystal form  $P2_12_12$ . Lastly, while the products of Group VI contain data obtained from crystals of enzymes having decarbamylase activity, they do not contain data that describes the special technical feature of Group I and, more importantly, they have an entirely different physical composition from the decarbamylase crystal of Group I. Thus, the special technical feature of Group I is not shared by Groups IV and VI.

The methods of Groups III and V do not make or use the special technical feature of Group I. While these methods may make or use a decarbamylase or decarbamylase mutant, these decarbamylases have different structures from the decarbamylase of Group I because they

Art Unit: 1652

do not share both SEQ ID NO: 1, in its entirety, and the crystal form P2<sub>1</sub>2<sub>1</sub>2. Examiner notes that claim 32 of Group V utilizes the stereostructure of the decarbamylase crystal of Group I; however, the stereostructure of the decarbamylase crystal of Group I has a different physical composition from the decarbamylase crystal of Group I, thus, it has different structural features. The special technical feature of Group I is not shared by Groups III and V.

### ***Election***

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lindsay Odell whose telephone number is 571-272-3445. The examiner can normally be reached on M-F, 8:00-4:30.

Art Unit: 1652

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lindsay Odell, Ph.D.  
April 12, 2005

  
KATHLEEN KERR, PH.D.  
PRIMARY EXAMINER